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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/834,309	04/11/2001	Xiaojiang Chen	2848-43	3032

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EXAMINER
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ART UNIT	PAPER NUMBER
1631	10

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
09 834,309	CHEN ET AL.
Examiner	**Art Unit**
Nikolai M Galitsky	1631

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4)☐ Interview Summary (PTO-413) Paper No(s) _____
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____

DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Drawings

Applicant is hereby notified that the required timing for the correction of the drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-948 (rev. 03/01 or earlier)". Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant applications or a notice of a failure to fully respond to this Office action.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I. Claims 1-27, drawn to a method of structure-based identification of compound using three-dimensional structure of a CR2, classified in Class 702, subclass 27. If this group is elected, then the below specie election requirement also is required.

Group II. Claim 28, drawn to a method to identify a compound that inhibits the complement receptor type 2(CR2)-dependent infection of a host cell by EBV, classified in Class 702, subclass 27.

Group III. Claims 29-30, drawn to a method to identify a compound that inhibits the binding of CD23 to complement receptor type 2(CR2), classified in Class 702, subclass 27.

Group IV. Claims 31-33, drawn to a method to identify a compound that inhibits the binding of C3d, C3 or a portion thereof, to complement receptor type 2(CR2), classified in Class 702, subclass 27.

Group XI. Claim 34, drawn to a method to inhibit CR2-dependent HIV-1 infection of cell in a patient, classified in Class 702, subclass 27.

Group VI. Claim 35, drawn to a method of preparing a vaccine, classified in Class 424, subclass 9.2 and Class 702, subclass 27.

Group VII. Claim 36, drawn to a drug delivery system, classified in Class 514, subclass 2.

Group VIII. Claims 37 and 38, drawn to an antibody that selectively binds to CR2, classified in Class 530, subclass 387.1. If this group is elected, then the below specie election requirement also is required.

Group IX. Claim 39, drawn to a crystal of receptor type 2 (SEQ ID NO: 4) in complex with C3d (SEQ ID NO: 7) at resolution greater than 2.0Å, classified in Class 436, subclass 4.

Group X. Claim 40, drawn to a therapeutic composition, classified in Class 702, subclass 27.

Group XI. Claims 41-44, drawn to a therapeutic composition, classified in Class 702, subclass 27. If this group is elected, then the below specie election requirement also is required.

Group XII. Claim 45, drawn to a method of preparing complement receptor type 2 proteins having modified biological activity, classified in class 703, subclass 27.

Group XIII. Claims 46-47, drawn to an isolated C3d mutant protein, classified in Class 530, subclass 350. If this group is elected, then the below specie election requirement also is required.

The inventions are distinct, each from the other because of the following reasons:

Methods I-VI are distinct from products of VII-XIII because the products as claimed can be used in materially different processes of using those products.

The inventions of Groups I - VI are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.05). The inventions of Groups I-VI are directed to the distinct computational methods of drug design using three dimensional structure of a CR2 for identifying a compound that can interact with active sites of CR2. In the instant case, the distinct claimed inventions have different function; modes of operations and can produce different results. For example, the invention I is distinct from invention II as the invention II is directed to a method of identifying a compound that inhibit the complement receptor type 2 (CR2)-dependent infection of a host cell by Epstein Barr Virus (EBV), whereas the invention I is directed to a method of structure-based identification of compounds which potentially bind to complement receptor type 2 (CR2) proteins or complex of CR2 and its ligand. Also, these inventions are practiced under different conditions in which said EBV particle can bind to CR2 and infect the cell or a CR2-CR2 ligand complex can form in the absence of said candidate compound. Different conditions can produce different results.

Inventions I - VI are distinct from Invention VII as a drug delivery system is used in the invention of Group VII and not required in the methods of identifying a compound of Groups I - VI.

Inventions I - VI are distinct from Invention VIII as an antibody is the invention of Group VIII and not required in the methods of identifying a compound of Groups I - VI.

The inventions of Group IX and Groups I - VI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case a crystallized molecule or molecular complex of CR2 with C3d of Group IX is used in alternative methods of Groups I and VI, drawn to a method for identifying an compounds that bind to CR2 proteins with an active sites and a method of preparing a vaccine, respectively. In addition, the crystallized complex of CR2 protein can be used in a method, for example, of homology modeling, which is also a clearly distinct usage of a crystal data.

The inventions of Groups I - VI and Groups X and XI are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.05). The inventions of Groups I - VI are directed to the computational methods of drug design using three dimensional structure of a CR2 for identifying a compound that can interact with active sites of CR2, whereas the invention of Group X, for example, is directed to a therapeutic composition, that administered to an animal, enhances B cell responses in said animal. In the instant case, the different claimed inventions are distinct methods, which have different function; modes of operations and can produce different results.

Inventions I - VI are distinct from Invention XII as method of preparing complement receptor type 2 proteins having modified biological activity is used in the invention of Group XII and not required in the methods identifying compound of Groups I - VI.

The inventions of Groups I - VI and Group XIII are related as methods of identifying and product. In the instant case an isolated protein of Group XIII practices in distinct inventions of Groups I and IX, drawn to a computational method using three dimensional structure of a CR2 for identifying a compound that can interact with active sites of CR2 and a crystal of receptor type 2 in complex with C3d at resolution greater than 2.0Å, respectively. In addition, the protein of Group XIII can be practice as a drug, which is also a clearly distinct usage of the agent.

Invention VIII is distinct from Invention VII as a drug delivery system is used in the invention of Group VII and not required in the invention of Group VIII, which is directed to an antibody that selectively binds to CR2.

Invention IX is distinct from Invention VII as a drug delivery system is used in the invention of Group VII and not required in the invention of Group IX, which is directed to a crystal of receptor type 2 in complex with C3d at resolution greater than 2.0Å

Inventions X-XI are distinct from Invention VII as a drug delivery system is used in the invention of Group VII, whereas the invention of Groups X-XI are directed to the therapeutic compositions, which are administered to an animal.

Invention XII is distinct from Invention VII as a drug delivery system is used in the invention of Group VII and not required in the invention of Group XII, which is directed to a method of preparing complement receptor type 2 proteins having modified biological activity.

Invention XIII is distinct from Invention VII as a drug delivery system is used in the invention of Group VII and not required in the invention of Group XIII, which is directed to an isolated C3d mutant protein.

Invention IX is distinct from Invention VIII as an antibody that selectively binds to CR2 is used in the invention of Group VIII and not required in the invention of Group IX, which is directed to a crystal of receptor type 2 in complex with C3d at resolution greater than 2.0Å.

Inventions X-XI are distinct from Invention VIII as an antibody that selectively binds to CR2 is used in the invention of Group VIII and not required in the invention of Groups X-XI, which are directed to the therapeutic compositions, which are administered to an animal.

Invention XII is distinct from Invention VIII as an antibody that selectively binds to CR2 is used in the invention of Group VIII and not required in the invention of Group XII, which is directed to a method of preparing complement receptor type 2 proteins having modified biological activity.

Invention XIII is distinct from Invention VIII as an antibody that selectively binds to CR2 is used in the invention of Group VIII and not required in the invention of Group XIII, which is directed to an isolated C3d mutant protein.

The inventions of Groups X-XI and Group IX are distinct. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05). In the instant case a crystallized molecule or molecular complex of CR2 with C3d of Group IX is used in alternative inventions of Groups I and X-XI, drawn to a method for identifying an compounds that bind to CR2 proteins with an active sites and the therapeutic compositions, respectively. In addition, the crystallized complex of CR2 protein can be used in a method, for example, of homology modeling, which is also a clearly distinct usage of a crystal data.

The inventions of Group XII and Group IX are related as process of use and product. In the instant case a crystallized molecule or molecular complex of CR2 with C3d of Group VII is used in alternative methods of Groups I and XII, drawn to a method for identifying an compounds that bind to CR2 proteins with an active sites and a method of preparing complement receptor type 2 proteins, respectively. In addition, the crystallized complex of CR2 protein can be used in a method, for example, of homology modeling, which is also a clearly distinct usage of a crystal data.

Invention XIII is distinct from Invention IX as a crystal of receptor type 2 in complex with C3d at resolution greater than 2.0Å is used in the invention of Group IX and not required in the invention of Group XIII, which is directed to an isolated C3d mutant protein.

Inventions XII are distinct from Inventions X-XI as therapeutic compositions are used in the invention of Group X-XI and not required in the invention of Group XII, which is directed to a method of preparing complement receptor type 2 proteins.

Inventions XIII are distinct from Invention X-XI as therapeutic compositions are used in the invention of Groups X-XII and not required in the invention of Group XIII, which is directed to an isolated C3d mutant protein.

The inventions of Group XIII and Group XII are distinct. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case a structure defined by atomic coordinates derived from CR2 protein of Group XIII is used in alternative inventions of Groups I and X, drawn to a method for identifying an compounds

that bind to CR2 proteins with an active sites and a therapeutic composition, respectively. In addition, the atomic coordinates derived from CR2 protein can be used in a method, for example, of homology modeling, which is also a clearly distinct usage of a crystal data.

All Groups would require a distinct and different search with minimal overlap thus documenting the undue search burden of searching.

SPECIE ELECTION REQUIREMENT FOR GROUPS I, II, VI, VIII and X:

This application contains claim directed to the following patentably distinct species of the claimed invention: These species are distinct because they each add a feature to a crystal of an CR2 protein for binding site or ligands with different structures and distinct functions. Also, these inventions are practiced under different conditions in which, for example, a EBV particle can bind to CR2 and infect the cell or a CR2-CR2 ligand complex can form in the absence of said candidate compound. Different conditions can produce different results, which each would require a separate and burdensome search to add to the search for the basic detection molecule as defined above.

Group I:

Specie IA: candidate compounds that inhibit the binding of CR2 to its ligand (claims 3-7);

Specie IB: candidate compounds that stabilizes a complex of CR2 with its ligand (claims 8-11);

If the specie A or B is elected, then an election one of next specie is also required:

Specie I-1: claim 12;

Specie I-2: claim 13;

Specie I-3: claim 14;

Specie I-4: claim 15;

Specie I-5: claim 16;

Specie I-6: claim 17;

Specie I-7: claim 18;

Specie I-8: claim 19;

Specie I-9: claim 20;

Specie I-10: claim 21;

Specie I-11: claim 22;

Specie I-12: claim 23;

If the one specie from I-12 to I-23 is elected, then an election one of next specie is also required:

Specie I-a: claim 24;

Specie I-b: claim 25;

Specie I-c: claim 26;

Specie I-d: claim 27.

Group VIII:

Specie VIII-A: the interface between the SCR1 and SCR2 domains of CR2;

Specie VIII-B: the dimmer interface between two CR2 proteins;

Specie VIII-C: the interface between CR2 and C3d;

If the specie VIII-C is elected, then an election one of next specie is also required:

Specie VIII-CD: the B strand and B-C loop of CR2 SCR2 comprising the segment: G79-G80-Y81-K82-I83-R84-G85-S86-T87-P88-Y89.

Specie VIII-CE: the B strand of CR2 SCR2 comprising position K100;

Specie VIII-CF: a segment of CR2 SCR2 comprising V130-F131-P132-L133;

Specie VIII-CG: a segment of CR2 SCR2 comprising T101-N102-F103.

Group XI:

Specie XI -A: a composition that stimulates the activity;

Specie XI -B: a composition that inhibits the biological activity;

Specie XI -C: a composition that inhibits the formation of a complex between CR2 and CR2 ligand;

Specie XI -D: a composition that inhibits the activation of CR2.

Group XIII:

Specie XIIIA: an amino acid sequence that differs from SEQ ID NO: 7 at positions 115, 116 and 170;

Specie XIIIB: SEQ ID NO: 8;

Specie XIIIC: SEQ ID NO: 9.

Applicants are advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added

after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, the specie elections for examination purposes as indicated is proper.

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR § 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikolai Galitsky, Ph.D., whose telephone number is (703) 308-2422. The examiner can normally be reached on Monday-Friday from 8:30 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

August 07, 2002

NMG

MICHAEL P. WOODWARD
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